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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,857	11/25/2003	Fred H. Burbank	ETH5293USNP	6931

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Doherty IP Law Group LLC
37 Belvidere Ave
Washington, NJ 07882

EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
07/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,857	BURBANK ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10-12,15-18,21,22 and 32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,15-18,21,22,34,39-41 and 43-46* is/are rejected.

7)☒ Claim(s) *11,12,32,33,35-38 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 10, 34, 40, 41, 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (US 5,562,680).

3. Hasson discloses an intravaginal device capable of occluding a female patient's uterine arteries with an unsymmetrical anatomy to treat a uterine disorder, comprising: a first occluding member having a first elongated shaft (14), a first operative proximal shaft section (88,90) configured to extend out of the patient during treatment, which has a first distal shaft section (18) with a first pressure applying occluding element (82) secured to the first distal shaft section (in that all the elements of the device are secured to each other), and a first mechanism/extending actuator (86, 92) to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section to a second position further away from the first operative proximal shaft section and for moving the first pressure applying surface distally away from the distal end of the first elongated shaft (Fig. 7; C6:L6-18); and a second occluding member (16) having a second elongated shaft, a second operative proximal shaft section configured to extend out of the patient during treatment and a

second distal shaft section with a second pressure applying occluding element secured to the second distal shaft section; and a connection (46) between the first and second occluding members which is configured to adjust spacing between the first and second pressure applying occluding elements (C5: L13-20) to press the pressure applying occluding elements against the patient's vaginal wall to occlude underlying uterine arteries. Regarding claim 41, the first and second extending actuators (86, 92) are respectively coupled to the first and second occluding elements (82) for selectively moving the first and second pressure applying surfaces between a first position closer to the proximal end of the device and a second position further away from the proximal end of the device. (When the two occluding members are pivoted apart as in Fig. 6 (first position), the proximal end is closer to the location of the pivot, as is the distal end having the pressure applying occluding element. When the two occluding members are in line with each other as in Fig. 1 (second position), the proximal end moves further from the location of the pivot in the proximal direction and the pressure applying occluding element at the distal end moves distally from the location of the pivot. Thus the second position results in the pressure applying surface being further away from the proximal end of the device than in the first position.) Regarding claim 2 the second occluding member has a second mechanism to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section (see Fig. 1 and above elements with respect to first occluding member). Regarding claims 3 and 40, the connection between the first and

second occluding members is a pivotal connection (Fig. 5 and 6; C5: L17). Regarding claim 4, each of the proximal shaft sections of the occluding members includes a finger engaging grip (C6:L10-15). Regarding claim 5, at least part of the first pressure applying occluding element is configured for positional adjustment in-line with the first distal shaft section (Fig. 7). Regarding claim 6, at least part of the first pressure applying occluding element is configured for rotation within a plane at or near the first distal shaft section (via pivot at connection (46) in Fig. 6). Regarding claim 10, the first pressure applying occluding element includes an occlusion bar with a pressure applying surface (any of the fingers can be an occlusion bar with a pressure applying surface). Regarding claim 45, the first and second occluding elements are movable along the longitudinal axis (Fig. 7). Regarding claim 46, the first and second occluding elements are movable independently of one another.

4. Claims 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schifano (US 5,591,173).

5. Schifano discloses the invention substantially as claimed including a device having a distal end, a proximal end and a longitudinal axis; a first and occluding member which has a first elongated shaft (12) a first occluding element (15) secured to the end of the elongated shaft, the first occluding element having a first pressure applying surface (for example 19) at a distal end thereof, and a first extending actuator (14) coupled with the first occluding element for selectively moving the first pressure applying surface between a first position closer to the proximal end of the device and a

second position further away from the proximal end of the device. (When the device is open as in Fig. 4, the length of the device is shorter and the proximal end is closer to the distal end. When the device is closed as in Fig. 5, the device lengthens and the occluding element at the distal end is moved further away from the proximal end of the device.) There is a second occluding member having the same features as the first occluding member stated above and having second elongate shaft (11) pivotally connected (13) with the first elongated shaft for adjusting spacing between the first and second pressure applying surfaces.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Malecki (US 6,368,340).

8. Hasson discloses the invention substantially as claimed as stated above including a mechanism that extends the occlusion element distally away from the distal

shaft section, but does not disclose that the mechanism for extending the occlusion element is effected by fluid under pressure.

9. Malecki discloses a clamp assembly that utilizes a hydraulic actuator for moving the occlusion element (C 20: L28-53). Malecki states that the use of a hydraulic system is an advantage because it does not take up much room in a trocar sleeve and enhances visualization (C 18: L 55-60).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydraulic system in place of the biasing springs into the invention of Hasson. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the hydraulic system is an enhancement over the mechanism used by Hasson for the reasons taught by Malecki and stated above.

10. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680).

11. Schifano fails to particularly disclose that the occluding member is displaced a distance of up to about one inch of between 0.25 to 0.8 inch from the distal shaft section. However, it would have been obvious to displace the occluding member a varied distance of up to about one inch or between 0.25 to 0.8 inch from the distal shaft section in order to make the device of a sufficient size to be used to occlude uterine

arteries. See Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

12. **Claims 15-18, 36, 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Hossack et al (US 6,045,508).**

13. Schifano discloses the invention substantially as claimed above but fails to disclose a blood flow sensor.

14. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51). Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Hasson, in order to monitor blood flow to ensure that too much pressure is not being applied. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the device can be measured.

15. **Claim 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (5,591,173) in view of Hossack et al (US 6,045,508).**

16. Schifano discloses the invention substantially as claimed above but fails to disclose a blood flow sensor.

17. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51).

Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Schifano, in order to determine when the blood flow has been successfully occluded. It is also old and well-known in the art to have blood flow sensors in occlusion devices. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the portion that is occluded can be measured.

Allowable Subject Matter

18. Claims 11, 12, 32, 33, 35, 37, 38 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

19. Applicant's arguments with respect to claim1-8, 10-12, 15-18, 21, 22, 32-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731
/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731

Notice of References Cited	Application/Control No. 10/721,857	Applicant(s)/Patent Under Reexamination BURBANK ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,582,451 B1	06-2003	Marucci et al.	606/207
*	B	US-6,656,205 B1	12-2003	Manhes, Hubert	606/205
	C	US-			
	D	US-			
	E	US-			
	F	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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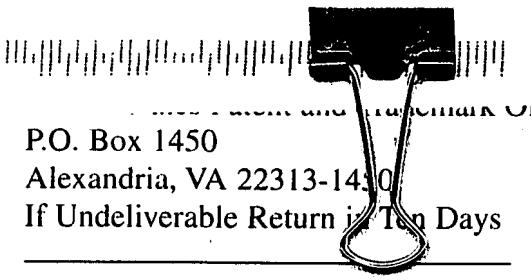
*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



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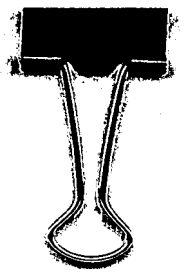

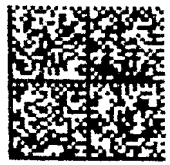

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